Title: MAGNETIC PULSE STIMULATION APPARATUS AND MAGNETIC FIELD SOURCE THEREOF

Abstract: The present invention relates to medical equipment, and more particularly to an apparatus for pulse magnetic stimulation of various organs and systems of various organs and systems of the human body. To provide wide application of a method of magnetic stimulation and to design a fairly inexpensive and reliable apparatus for magnetic stimulation, it is necessary first of all to increase the rate of magnetic induction rise up to the value of $\Delta B/\Delta t=10^5$ T/sec. The latter will make it possible to considerably reduce energy consumption of an apparatus for magnetic stimulation, to increase pulse repetition up to 1-2 kHz with the duration of an efficient stimulation pulse being increased up to $t_p=1$ sec and more, i.e. to provide the modulation frequency of about 30 pulse trains per minute. The object of the invention set forth in the apparatus for magnetic stimulation comprised of an oscillatory circuit containing a capacitor and a source of unipolar magnetic field pulses, said source further comprising a winding, a power supply unit and a storage capacitor, said capacitor connected in parallel to a capacitor in the oscillatory circuit, and also first and second controlled switches, and first and second diodes is achieved by providing said magnetic field source with a core made of soft magnetic composite material.
Apparatus for Magnetic Pulse Stimulation and Magnetic Field Source Thereof

Field of the Invention

The present invention relates to medical equipment, and more particularly to an apparatus for pulse magnetic stimulation of various organs and systems of the human body.

Prior Art

Stimulation of the central and peripheral nervous systems as well as of various internal organs of the human body by pulsed magnetic fields principally consists in the optimization of the process of creating in the desired area of an induced electric field with the magnitude of said field being sufficient to promote the activity of one or other process.


One of the major problems of magnetic stimulation is the optimization of magnetic field distribution near the source, including the orientation of a magnetic induction vector in relation to the surface being stimulated. While considering this problem two basic types of stimulation can be distinguished i.e. bipolar stimulation and unipolar one.

In case of bipolar stimulation the direction of a magnetic induction vector $\mathbf{B}_\parallel$ will be parallel in relation to the surface being stimulated. In this instance the circulation of an induced electric field is normal in relation to the surface being stimulated:

$$\text{rot} \; \mathbf{E} = - \frac{dB}{dt} \quad (1)$$

The induced circular electric field results in the creation of an electric current with the value of said current depending on the total specific resistance ($\rho$) of the internal layers $\rho_i$ and the skin $\rho_s$.

$$\rho = \rho_i + \rho_s \quad (2)$$

Since the specific resistance of the skin is much higher than the resistance of the internal layers,

$$\rho_s \gg \rho_i \quad (3)$$

the magnitude of an induced current in case of bipolar stimulation will be minimal.

This drawback has been eliminated in a method of unipolar stimulation, wherein the direction of a magnetic induction vector $\mathbf{B}_\perp$ is normal in relation to the surface being stimulated. The latter determines the circulation direction of an electric field intensity vector directly in soft tissues featuring low specific resistance. As a result, the
magnitude of current induced with unipolar stimulation is substantially higher than that induced with bipolar stimulation.

As follows from the above, the efficiency of a unipolar method of stimulation by pulsed magnetic fields will be substantially higher than that of bipolar stimulation. In this connection the magnetic stimulation by a bipolar stimulation circuit disclosed in [11] and in a number of other references seems to be less efficient as compared to a unipolar one.

Much higher efficiency of a unipolar method of stimulation by pulsed magnetic fields determines the design parameters of a pulsed magnetic field source.

Most essential for magnetic stimulation is the optimization of magnetic field pulse characteristics i.e. its shape, amplitude and duration.

In [12] the most frequently occurring shapes of magnetic field pulses and the circuit for generating thereof are described. A magnetic field pulse similar in shape to a triangular one is generated during the discharge of the capacitor bank C while the switch S is closed into the induction coil L. The circuit parameters i.e. inductance L, capacitance C and resistance R define a rise time of a magnetic field pulse as in the case described to \( t_r = 100 \) microseconds. After the capacitor C is fully discharged causing the current through the inductance coil and the value of the magnetic field to decrease, the energy of the magnetic field is converted into the heat energy on resistor R. The circuit of the above-described type is very inefficient, since the energy supplied to generate a magnetic field is further converted into the heat energy.

A magnetic field pulse similar in its shape to a semi-sinusoidal one is generated when the capacitor \( C_1 \) is discharged into the inductance coil L after the closure of the switch \( S_1 \), and the magnetic field energy is further discharged into the capacitor \( C_2 \) after the closure of the switch \( S_2 \). In this case the total duration of a magnetic field pulse for the above circuit parameters is \( t_p = 350 \) microseconds for pulse rise and decay times being in symmetry.

An important distinguishing feature of the above-described circuits is the divergence in the shapes of an electric field induced voltage pulse. In the first case the shape of an induced voltage pulse is practically unipolar due to significant difference between pulse
rise and pulse decay times. In contrast to it in the second case the shape of an induced voltage pulse is similar to a sinusoidal one.

As it follows from the analysis of the data concerning the research on magnetic stimulation both shapes of magnetic field pulses have nearly similar applicability.

One of the most vital problems concerning the efficiency of magnetic stimulation is the duration of a magnetic field pulse i.e. pulse rise and pulse decay times. In [12] the duration of a magnetic field pulse makes up the value of \( t_p = 350 \) microseconds. As opposed to the above, in one of the recent papers [13] the value of the proposed duration of a magnetic field pulse similar in shape to a triangular one is given as \( t_p = 0.4 \) sec. Approximately the same duration of a magnetic field pulse similar in shape to a semi-sinusoidal one is reported in [14].

As shown by the research of the influence of the magnetic field pulse duration on the stimulation efficiency of the central and peripheral nervous systems, the stimulation efficiency is increased with the increase in pulse duration. In this connection to improve the stimulation efficiency in some apparatus there is incorporated a parallel connection of several discharge chains [15].

The duration of a magnetic field pulse is used to define the energy consumption required for magnetic stimulation. Pulse duration being of \( t_p = 350 \) microseconds [12], the magnitude of pulse current of \( I_p = 3000 \) A and capacitor voltage of \( U = 1500 \) V, when the capacitor is discharged into the coil without a magnetic core, the energy required for generating a magnetic field pulse will be

\[
E = U \cdot I_p \cdot t_p = 1.5 \, \text{kJ} \quad (4)
\]

Similar high-energy storage apparatus is heavy and costly and not very reliable in operation.

The most closely related example of an apparatus and a method in accordance with the present invention is that described in [9]. The apparatus for magnetic stimulation is comprised of an oscillatory circuit containing a capacitor and a source of unipolar magnetic field pulses, said source further comprising a winding, a power supply unit and a storage capacitor, said capacitor connected in parallel to a capacitor in the
oscillatory circuit, and also first and second controlled switches, and first and second diodes. A method of magnetic stimulation by the apparatus described consists in locating a butt-end of a source winding in the desired area on the patient head and further generating unipolar magnetic field pulses. In implementation of a method described a magnetic field source is placed in a Dewar vessel for decreasing its resistance due to superconductivity effect. The complexity of the design is beyond question.

Some of these characteristics could be improved by making a magnetic field source of high-induction ferromagnetic material such as vanadium permendur [16]. However, in this case the rate of magnetic field rise up due to eddy current losses could not be high and amounts to 20-30 T/sec. With the capacitor bank being discharged into the coil without a magnetic core, this value becomes substantially higher and makes up about 2000-3000 T/sec.

The rate of magnetic induction rise up actually defines the efficiency of magnetic stimulation i.e. the value of an electric field induced potential. Naturally, an increase in the rate of magnetic induction rise up will make it possible to reduce the utmost realizable induction of a magnetic field and hence the energy consumption to achieve the same values of an induced voltage.

The indicated rate values of magnetic induction rise up for coils both with and without a magnetic core are practically utmost realizable, since an increase in a magnetic field magnitude requires a substantial increase in a capacitor bank i.e. L, C, R parameters of a discharge circuit and, as a result, a decrease in the rate of magnetic induction rise up.

All this results in the fact that despite great promise offered by a method of magnetic stimulation, the apparatus thereof have very limited application due to their high cost, large dimensions and low operating reliability.

The most closely related prototype of the source of unipolar magnetic field pulses is that described in [10] which is comprised of at least two helix-shaped windings with a butt-end of one of said windings being located on the patient body.

Summary of the Invention
To provide wide application of a method of magnetic stimulation and to design a fairly inexpensive and reliable apparatus for magnetic stimulation, it is necessary first of all to increase the rate of magnetic induction rise up to the value of $\Delta B/\Delta t = 10^5$ T/sec. The latter will make it possible to considerably reduce energy consumption of an apparatus for magnetic stimulation, to increase pulse repetition up to 1-2 kHz with the duration of an efficient stimulation pulse being increased up to $t_s = 1$ sec and more, i.e. to provide the modulation frequency of about 30 pulse trains per minute.

The object of the invention set forth in the apparatus for magnetic stimulation comprised of an oscillatory circuit containing a capacitor and a source of unipolar magnetic field pulses, said source further comprising a winding, a power supply unit and a storage capacitor, said capacitor connected in parallel to a capacitor in the oscillatory circuit, and also first and second controlled switches, and first and second diodes is achieved by providing said magnetic field source with a core made of soft magnetic composite material.

A positive lead of an oscillatory circuit capacitor is connected to the first lead of a magnetic field source winding through the first switch and to the second lead of said source through the first diode, while a negative lead of an oscillatory circuit capacitor is connected to the second lead of said source through the second switch, and the first lead of said source is connected through the second diode, while said first and second diodes are connected in reverse direction.

The above-mentioned controlled switches are made as high frequency transistors featuring low output resistance with the control electrodes of said transistors serving as inputs for a device for supplying the control signals.

The transistors described above are IJBT-transistors.

Positive leads of a storage capacitor and an oscillatory circuit capacitor are coupled through a high frequency choke and their negative leads are directly connected.

The apparatus is provided with first and second variable delay means connected in series to corresponding diodes.
In a method of magnetic stimulation therapy consisting in stimulation by a magnetic stimulation therapy apparatus comprised of an oscillatory circuit containing a capacitor and a source of unipolar magnetic field pulses, said source further comprising a winding, a power supply unit and a storage capacitor, said capacitor connected in parallel to a capacitor in the oscillatory circuit, and also first and second controlled switches, and first and second diodes, said stimulation being effected by means of locating a butt-end of said source winding on a desired part of the patient body and further generating unipolar magnetic field pulses, the aim set forth is achieved by providing said source with a core made of soft magnetic composite material.

Magnetic field pulses are generated with the shape similar to a triangular one.

Pulse decay time of a magnetic field pulse is controlled in the range from $10^{-5}$ to $10^{-3}$ seconds.

The trains of magnetic field pulses are generated.

The trains of magnetic field pulses are generated with the frequency of pulses within a train varying from 10 to 1000 Hz.

The repetition rate of the trains of magnetic field pulses is made ranging from 20 to 60 trains per minute.

In a source of magnetic field pulses having at least two helix-shaped windings with a butt-end of one of said windings intended for locating on the patient body the aim set forth is achieved by providing said source with a core made of soft magnetic composite material.

The core of a magnetic field source is made in the shape of a hollow cylinder with an outer surface of said cylinder enclosed by one of said helix-shaped windings, while the other winding connected in opposition is enclosed by the inner surface of said core.

The height $h$ and the outer diameter $d_e$ of the core are chosen from proportion $h/4 < d_e < h$ with the outer diameter of the core $d_e$ exceeding its inner diameter $d_i$ by 10 to 30 mm.

**Brief Description of the Drawings**
Fig. 1 is a generalized block-diagram of an apparatus in accordance with present invention.

Fig. 2 is a block-diagram of an apparatus with two magnetic field sources.

Fig. 3 are time charts of a magnetic field created by the apparatus in accordance with the present invention.

Fig. 4 is a time chart of a voltage-induced pulse.

Fig. 5 is a schematic representation of a source of magnetic field pulses shown in a lengthwise section.

Fig. 6 are time charts of magnetic field pulses generated by the source in accordance with the present invention (A), by a magnetic field source without a core [12] (B) and by the source with a core made of vanadium permendur [13] (C).

Detailed Description of the Invention and Preferable Examples

A generalized block-diagram of a magnetic stimulation apparatus in accordance with the present invention is shown in Fig. 1. An apparatus in accordance with the present invention is comprised of an oscillatory circuit containing a capacitor 1 and a source 2 of unipolar magnetic field pulses, a power unit 3, a storage capacitor 4. Positive lead of an oscillatory circuit capacitor 1 is connected to the first lead of the source 2 through the first switch 5 and to the second lead of the source 2 through the first diode 6. Negative lead of the oscillatory capacitor 1 is connected to the second lead of the source 2 through the second switch 7 and to the first lead of the source 2 through the second diode 8. First and second diodes are connected in reverse direction. Positive leads of capacitors 1 and 4 are coupled through a high-frequency choke 9. Control electrodes of said transistors serve as inputs for a device for supplying control signals. In the example described these are supplied with similar signals. First and second variable delay means 10 and 11 are connected in series to diodes 6 and 8.

The method of the present invention is implemented as follows.

The magnetic field source 2 is located on the part of the patient body suffering from a disorder. It may be head, extremities or others parts of body.
The capacitor 1 is supplied with the voltage from the power supply unit 3 until the capacitor is fully charged.

When the control electrodes of transistors i.e. switches 5 and 7 are simultaneously supplied with a pulsed signal, the magnetic field source 2 will generate a magnetic field pulse as shown in Fig.3.

Should the magnitude of a magnetic field be decreased after said transistors are turned off, a decay time of said magnetic field pulse is formed. The decay time of said magnetic field pulse can be varied from $5 \times 10^{-5}$ to $10^{-3}$ seconds by means of first 10 and second 11 variable delay means.

An induced voltage of reverse polarity in the source 2 is inverted by means of diodes 6 and 8, and the energy is returned into the capacitor 1 in an oscillatory circuit.

The recovery of active losses in an oscillatory circuit is effected simultaneously by supplying the energy through the high-frequency choke 9 from the storage capacitor 4. Thus, during a decay time of a magnetic field pulse the voltage on the capacitor 1 is restored to its rated value.

The second magnetic field pulse could be generated actually after the first discharge pulse is terminated.

The control electrodes of the transistors, i.e. switches 5 and 7, are supplied with the series of pulsed signals of pre-defined frequency and in pre-defined amount to generate the trains of magnetic field pulses in the way described with the frequency of said pulses within a train varying from 10 to 1000 Hz and repetition rate of the trains of magnetic field pulses varying from 20 to 60 trains per minute.

Each of the above-described magnetic field pulses induces an electric field potential pulse in the patient tissues as shown in Fig.4. It is evident that the shape of this pulse and hence its specific stimulation efficiency are dependent on the magnetic field pulse being generated. For a very short decay time of a magnetic field pulse (curve (a) in Fig.4) said potential pulse is a bipolar one (curve a in Fig.4), and, with the magnetic field decay time being increased, a potential pulse becomes a unipolar one (curve (b) in Fig.4 respectively).
The circuit diagram of an apparatus with two magnetic field sources (15 and 16 respectively) made with the cores of soft magnetic composite material with the diameter of said cores $d_a$ = 100 and 40 mm is shown in Fig.2. The peculiar feature of the apparatus circuit in accordance with the present invention is that the energies of the capacitors 17 and 18 in the oscillatory circuits are much higher than the energy of a magnetic field pulse:

$$E_{100} \ll C_{17}.U^2/2 \text{ или } E_{40} \ll C_{18}.U^2/2,$$

In this connection, should the transistor switches, e.g. 19 and 20, be opened and the capacitor 17 be discharged into the magnetic field source 15, the voltage on the capacitor 17 is decreased by maximum 20%. After the closure of transistor switches 19 and 20 the voltage on a magnetic field source is inverted with the energy of a magnetic field pulse being returned into the capacitor 17 after opening of diodes 21 and 22. Simultaneously the recovery of active losses in an oscillatory circuit occurs by means of the energy being supplied from storage capacitors 24 and 25 through the high-frequency choke 23. Actually during the decay time of a magnetic field pulse the voltage on the capacitor 17 is restored to its rated value. In content of all the above-said the second magnetic field pulse can be generated just after the first discharge pulse is terminated.

The operation of the second oscillatory circuit (magnetic field source 15, capacitor 18, transistor switches 19' and 20', diodes 21' and 22' and high-frequency choke 23') is similar to the first one but it occurs with a time-shift equal to the duration of a discharge pulse in the first oscillatory circuit.

A magnetic field source of the present invention is illustrated in Fig.5.

To provide the circulation of an induced electric current inside the patient body in the plane parallel to its surface a magnetic field source is provided with two helix-shaped windings 12, 13 and the core 14 made of soft magnetic composite material. The core 14 is made as a hollow cylinder with an outer side surface of said cylinder enclosed by the winding 12, while the other winding 13 connected in opposition is enclosed by the inner surface of the core 14. To enhance a magnetic field induction in the pulse up to $B_m=2.2$ T on the surface of a magnetic field source and to increase a magnetic field penetration depth, the height $h$ of the core 14 is chosen from the proportion
\[ h/4 < d_e < h, \]

where \( d_e \) is an outer core diameter. The outer diameter \( d_e \) of the core exceeds its inner diameter \( d_i \) by 10 to 30 mm.

The soft magnetic composite material is an iron-based composite with each iron particle being covered by a thin layer of magnetic dielectric, e.g. SMC-500 of Hoganas AB Co. (Sweden) and, as opposed to metal ferromagnetic material, it does not feature any eddy current losses. As a result a magnetic permeability frequency characteristic is shifted towards higher frequencies as compared to that of metal ferromagnetic material.

The field dependencies of the magnetic induction for metal magnetic material and for soft-magnetic composite material greatly differ in the initial part of the curves. When the intensity of the magnetic field reaches the value of more than \( H = 10 \) kA/m, the behavior of magnetization curves will be actually the same. Soft-magnetic composite materials are characterized by almost linear variation of magnetic induction with magnetic field variation. The major characteristics of a soft-magnetic composite material are as follow:

- Magnetic permeability mean value \( \mu = 200 \)
- Magnetic induction saturation value \( B_m = 2.2 \) T

The induction \( L \) of a magnetic field source with a core of soft-magnetic composite material actually retains its value just as for a magnetic field source without a core due to the reduction in a number of turns:

\[ L = \mu_0 \cdot \mu \cdot n^2 \cdot V = 20 \cdot 10^{-6} \text{ H} \]

The capacitance value of the capacitor 1 in an oscillatory circuit is decreased as compared to the previous cases to \( C = 10 \) \( \mu \)F. As a result the magnetic induction rise time is determined by

\[ T/4 = 0.5 \pi \sqrt{L \cdot C} = 20 \cdot 10^{-6} \text{ sec} \]

Accordingly the rate of the magnetic induction rise time will be come to

\[ \Delta B/\Delta t = 10^5 \text{ T/sec} \]
The total duration of a magnetic field pulse with rise up and decay times being in symmetry will be \( t_p = 50 \) microseconds.

Fig.6 shows minimum duration times of magnetic field pulses for the following sources: a source in accordance with the present invention with a core of soft magnetic composite material (curve 1), a source without a magnetic core (curve 2) and a source with a core of vanadium permendur (curve 3).

The energy required for generating a magnetic field pulse with induction of said field \( B = 1\)T for a source without a core of magnetic material is defined by

\[
E_1 = B^2 t_p / 2 \cdot \mu_0
\]

For a source with a magnetic core made of vanadium permendur or soft-magnetic composite material the required energy is defined as \( E_2 \) and \( E_3 \) accordingly:

\[
E_2, \ E_3 = B^2 t_p / 2 \cdot \mu_0 \cdot \mu
\]

By substituting the values of the parameters in the above expression it is possible to define the proportion of energies required for generating a magnetic field pulse with the induction of said field \( B = 1\) T by a source without a magnetic core \( E_1 \), a source with a core made of vanadium permendur \( E_2 \) and a source with core of magnetic composite material \( E_3 \):

\[
E_1 : E_2 : E_3 = 600 : 200 : 1
\]

As follows from the above equation the energy required by a magnetic field source of the present invention is almost three times less than for a source without a magnetic core or with a core made of vanadium permendur. Relatively small energy (2-3 J) consumed during generating a magnetic field pulse by a source with a core made of magnetic composite material makes it possible to do away with traditional high-voltage components such as thyristors, high-power capacitors etc. and to make use of high-power transistors type IGBT.
Claims:

1. An apparatus for magnetic pulse stimulation comprising an oscillatory circuit, said circuit including a capacitor and a magnetic field source of unipolar pulses, said source further comprising a winding, a power supply unit and a storage capacitor, said capacitor connected in parallel to an oscillatory circuit capacitor, and also first and second controlled switches, and first and second diodes, wherein said magnetic field source is provided with a core made of soft magnetic composite material.

2. An apparatus according to claim 1, wherein a positive lead of an oscillatory circuit capacitor is connected to the first lead of a magnetic field source winding through the first switch and to the second lead of said source through the first diode, while a negative lead of said oscillatory circuit capacitor is connected to said second lead of a magnetic field source through the second switch and to said first lead of a magnetic field source through the second diode, while said first and second diodes are connected in reverse direction.

3. Apparatus according to claims 1-2, wherein said controlled switches are high-frequency transistors with low output resistance, while the control electrodes of said transistors serve as inputs for a device for supplying the control signals.

4. An apparatus according to claim 3, wherein the transistors are IJBT transistors.

5. An apparatus according to claim 1, wherein positive leads of a storage capacitor and an oscillatory circuit capacitor are connected through a high-frequency choke and their negative leads are directly connected.

6. An apparatus according to claims 1-5, wherein said apparatus is provided with first and second variable delays means connected in series to corresponding diodes.

7. A method of magnetic stimulation therapy consisting in stimulation by a magnetic stimulation therapy apparatus comprised of an oscillatory circuit containing a
capacitor and a source of unipolar magnetic field pulses, said source further comprising a winding, a power supply unit and a storage capacitor, said capacitor connected in parallel to a capacitor in the oscillatory circuit, and also first and second controlled switches, and first and second diodes, said stimulation effected by means of locating a butt-end of a source winding in the desired area on the patient head and further generating the unipolar magnetic field pulses, wherein said magnetic field source is provided with a core made of soft magnetic composite material.

8. A method as in claim 7, wherein said magnetic field pulses are generated with the shape similar to a triangular one.

9. A method as in claim 7, wherein the decay time of magnetic field pulses is controlled in the range from $5 \times 10^{-5}$ to $10^{-3}$ seconds.

10. A method as in claims 7-9, wherein the trains of magnetic field pulses are generated.

11. A method as in claim 10, wherein said the magnetic field pulses within the train are generated with frequencies ranging from 10 to 1000 Hz.

12. A method as in claim 10, wherein the repetition rate of said trains of magnetic field pulses is made ranging from 20 to 60 trains per minute.

13. A source of unipolar magnetic field pulses comprised of at least two helix-shaped windings with a butt-end of one of said windings intended for locating on the patient body, wherein said source is provided with a core made of soft magnetic composite material.

14. A source as in claim 12, wherein said core is made as a hollow cylinder with an outer surface of said cylinder being enclosed by one of said windings, while the other helix-shaped winding connected in opposition encloses the inner surface of said core.

15. A source as in claim 13, wherein the height $h$ and the external diameter $d_e$ of the core are chosen from proportion $\frac{h}{4} < d_e < dh$, while the external diameter $d_e$ of said core exceeds its internal diameter $d_i$ by $10 - 30$ mm.
INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N2/02

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

<table>
<thead>
<tr>
<th>Category</th>
<th>Citation of document, with indication, where appropriate, of the relevant passages</th>
<th>Relevant to claim No.</th>
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<tbody>
<tr>
<td>A</td>
<td>GB 2 360 213 A (MAGSTIM CO LTD) 19 September 2001 (2001-09-19) page 2, line 14 -page 6, line 2; figures</td>
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<td>A</td>
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</table>

* Special categories of cited documents:

*A* document defining the general state of the art which is not considered to be of particular relevance

*E* earlier document but published on or after the international filing date

*L* document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

*O* document referring to an oral disclosure, use, exhibition or other means

*P* document published prior to the international filing date but later than the priority date claimed

*P* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

*8* document member of the same patent family

Further documents are listed in the continuation of box C.

X Patent family members are listed in annex.

Date of the actual completion of the international search: 14 February 2003

Date of mailing of the international search report: 21/02/2003

Name and mailing address of the ISA
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HT Rijswijk
Tel: (+31-70) 340-2040, Tx 31 651 epo nl, Fax: (+31-70) 340-3016

Authorized officer
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### DOCUMENTS CONSIDERED TO BE RELEVANT

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**INTERNATIONAL SEARCH REPORT**

**Box I** Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. **X** Claims Nos.: 7-12, because they relate to subject matter not required to be searched by this Authority, namely:
   - Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. **☐** Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. **☐** Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II** Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. **☐** As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. **☐** As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. **☐** As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. **☐** No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

**Remark on Protest**

- **☐** The additional search fees were accompanied by the applicant’s protest.
- **☐** No protest accompanied the payment of additional search fees.
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